

### **REMARKS**

This is in response to the Office Action mailed on December 10, 2008, in which claim 1 was objected to; claims 11-14 and 18-22 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter; claims 1-10 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,607,485 (“*Bardy*”) in view of U.S. Patent No. 6,669,631 (“*Norris*”) and further in view of U.S. Patent No. 6,644,322 (“*Webb*”); and claims 11-14 and 16-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Norris*. With this Amendment, claims 1 and 11 are amended. Claims 1-14, 16-26, and 28 are pending in the present application.

#### **Claim Objection**

Claim 1 was objected to because the phrase “from a second implantable medical device” was allegedly repeated in the claim. This phrase should read “from a second implantable medical device of a second implantable medical device type.” Claim 1 has been amended to reflect this, which cures the cited informality. Thus, it is respectfully requested that the objection to claim 1 be withdrawn.

#### **Claim Rejections – 35 U.S.C. § 101**

Claims 11-14 and 18-22 were rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. As noted in the recent Federal Circuit decision, *In re Bilski*, a claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. *In re Bilski*, 2007-1130, No. 2007-1130, slip op at 10 (Fed. Cir. Oct. 30, 2008). The Federal Circuit also noted that the “useful, concrete and tangible result” inquiry is inadequate and that the machine-or-transformation test is the proper test to apply. *Id.* at 20.

With this Amendment, claim 11 is amended to required that each of the recited method steps be performed by the medical device information system. This ties the elements of the process to a particular machine or apparatus – the medical device information system – in accordance with the test for patentable subject matter set forth in *Bilski*. Consequently,

because the method of claim 11 is directed to patentable subject matter, it is respectfully requested that the rejection of claims 11-14 and 18-22 under 35 U.S.C. §101 be withdrawn.

### **Claim Rejections – 35 U.S.C. § 103**

Claims 1-10 and 28 were rejected under 35 U.S.C. § 103(a), as being unpatentable over *Bardy* in view of *Norris* and further in view of *Webb*. Claim 1 recites a system for delivering and gathering medical information including a medical data set and a server. The server includes a process or and computer readable medium including instructions. The instructions are executable by the processor to, in part, (1) identify a review group by selecting from a collection of review group members capable of receiving the portion of the first data set under review through a communications network and returning an analysis of the portion of the first data set under review, wherein the review group includes a first member and a second member, (2) provide the portion of the first data set to the first and second members of the review group, and (3) receive a first analysis of the portion of the first data set from the first member of the review group and a second analysis of the portion of the first data set from the second member of the review group.

The Office Action states that *Bardy* fails to disclose the features listed above with regard to the instructions executed by the processor. To supply these deficiencies, the Office Action looks to *Norris*.

*Norris* discloses deep computing techniques that are applied to mine statistical databases and patient specific data files contributed from multiple sources to formulate patient-specific medical profile. The stated purpose of *Norris*'s system is to allow existing but widely scattered expert medical and biological knowledge and expertise to be combined in a database for the use in the routine (non-expert) treatment of chronic diseases. *Norris*, col. 11, lines 25-30. *Norris*'s data management system essentially allows non-experts to develop an analysis of data for a patient's implantable device using existing, recorded knowledge from experts, as well as stored data from other implantable devices similar to the patient's implantable medical device.

However, at no point does *Norris*'s data management system provide information from the patient's implantable medical device to a person or group of people for review and analysis. In other words, there is no human element to the analysis in *Norris*'s system. *Norris*'s system only mines existing, stored information to conduct an analysis. Consequently, *Norris* does not teach or suggest that the disclosed data management system identifies a review group including first and second members that are each capable of receiving data and returning respective first and second analyses of the data back to the system. This is an important distinction because having actual people (i.e., group members) review and analyze data from a patient's IMD allows patient-specific conditions and peculiarities to be recognized that might not otherwise be detected if the data is instead provided to a computer system for analysis (as in *Norris*'s system).

Claim 1 also requires that the instructions are executable by the processor to normalize the first and second analyses to provide a combined analysis of the first data set. As noted in paragraph 115 in the present application, the system might "adjust or normalize certain subjective data based on known physician biases." Alternatively, the system might "determine a statistical average for subjective information entered by a number of physicians, and discard any information that is not within the range of the average."

The Office Action states that neither *Bardy* nor *Norris* disclose that the processor normalizes first and second analyses to provide a combined analysis of the first data set. To supply this deficiency, the Office Action looks to *Webb*. *Webb* teaches a system and method for translating "Patient Session Information" including IMD data and patient data stored in IMD memory in one human language and optionally other patient data from other sources into another human language. In the passage cited in the Office Action, a user can employ XML to direct a markup language to define in-house data handling methods and normalize varied data input sources to allow complex data handling. The process of putting data in an appropriate format is very different from removing subjective biases or taking a statistical average. Consequently, *Webb* does not teach or suggest that the processor normalizes analyses as required by claim 1.

Therefore, because the prior art of record does not teach or suggest all limitations of claim 1, the rejection of claim 1 under § 103(a) should be withdrawn. Claims 2-10 and 28 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Norris* and further in view of *Webb*. Claims 2-10 and 28 depend from allowable claim 1, and as such are allowable therewith. In addition, it is respectfully submitted that the combinations of features recited in claims 2-10 and 28 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable. MPEP 2143.03.

Claims 11-14 and 16-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bardy* in view of *Norris*. With regard to claim 11, the Office Action states that *Bardy* fails to teach or suggest (1) identifying a review group associated with the first data set with the medical device information system by selecting from a collection of reviewers capable of receiving the first data set through a the communications network and returning an analysis of the first data set, wherein the review group includes a plurality of members; (2) communicating the first data set from the medical device information system to the members of the review group over the electronic communications network; (3) receiving an analysis of the first data set at the medical device information system from each of the members of the review group over the electronic communications network and combining the analyses of two or more of the members to provide a combined analysis for the first data set; (4) comparing the first data set with a second data set with the medical device information system to determine whether the first and second data sets are similar; and (5) associating the combined analysis of the first data set with the second data set with the medical device information system if the first and second data sets are determined to be similar.

With regard to claim 24, the Office Actions states that *Bardy* fails to teach or suggest a server including a processor and a computer readable medium with instructions executable by the processor to (1) receive a request for medical data, wherein the request includes an indication of the implantable medical device; (2) communicate the first data set to a first plurality of reviewers across a communication network and the second data set to a second plurality of reviewers across the communication network; (3) combine the medical analyses

of the first data set into a first combined analysis; and (4) combine the medical analyses of the second data set into a second combined analysis.

To supply the deficiencies of *Bardy*, the Office Action looks to *Norris*. As discussed above, *Norris* is directed to a data management system that allows non-experts to develop an analysis of data for a patient's implantable device using existing, recorded knowledge from experts, as well as stored data from other implantable devices similar to the patient's implantable medical device. At no point does *Norris*'s data management system provide information from the patient's implantable medical device to a person or group of people for review and analysis. In other words, there is no human element to the analysis in *Norris*'s system. *Norris*'s system only mines existing, stored information to conduct an analysis. Consequently, it cannot be said that *Norris* teaches that identifying a review group from a collection of reviewers capable of receiving the first data set through a the communications network, communicating the first data set to the members of the review group, or receiving an analysis of the first data set from each of the members, as required by claim 11. Similarly, *Norris* does not teach or suggest a processor that communicates the first data set to a first plurality of reviewers across a communication network and the second data set to a second plurality of reviewers across the communication network, as required by claim 24. Therefore, because the prior art of record does not teach or suggest all limitations of claims 11 or 24, the rejection of these claims under § 103(a) should be withdrawn.

Claims 12-14, 16-23, 25, and 26 were also rejected under 35 U.S.C. §103(a) as being unpatentable over *Bardy* in view of *Norris*. Claims 12-14 and 16-23 depend from allowable claim 11, and claims 25 and 26 depend from allowable claim 24. As such, these claims are allowable with their respective independent base claims. In addition, it is respectfully submitted that the combinations of features recited in claims 12-14, 16-23, 25, and 26 are patentable on their own merits, although this does not need to be specifically addressed herein since any claim depending from a patentable independent claim is also patentable. MPEP 2143.03.

### **CONCLUSION**

For the reasons explained above, all pending claims are now in condition for allowance. Accordingly, the applicant respectfully requests that the Office issue a Notice of Allowance.

Any amendments to the claims are made to expedite prosecution of this application, without acquiescing to the Office's rejections or characterizations of the claims or references in the Office Action. Even if not expressly discussed above, the applicant respectfully traverses each of the rejections, assertions, and characterizations regarding the disclosure and teachings of the cited references, including the prior art status and the propriety of proposed combinations of cited references.

The Applicant has made a good faith effort to respond to all rejections set forth in the Office Action and to place the pending claims in condition for immediate allowance. If it would be helpful, the Examiner is invited to contact the undersigned at the number listed below to facilitate prosecution of this application.

Respectfully submitted,

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